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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,934	12/31/2003	Thomas E. Tarara	0101.00	1899
21968	7590	12/28/2007		
NEKTAR THERAPEUTICS 201 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER SCHLIENTZ, LEAH H	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,934	Applicant(s) TARARA ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42, 44, 47-56, 58, 60, 62-68 and 84-103 is/are pending in the application.
- 4a) Of the above claim(s) 23-37 and 84-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 38-42, 44, 47-56, 58, 60, 62-68 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 10/06/2007, in reply to the Office Action mailed 5/11/2007, is acknowledged and has been entered. Claims 1 – 6, 8, 12, 20, 21, 38, 39, 41, 42, 44, 53, 54 and 60 have been amended. New claim 103 has been added. Claims 43, 45, 46, 57, 59, 61 and 69 – 83 have been cancelled. Claims 1 – 42, 44, 47 – 56, 58, 60, 62 – 68 and 84 – 103 are pending, of which claims 23 – 37 and 84 – 102 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1 – 22, 38 – 42, 44, 47 – 56, 58, 60, 62 – 68 and 103 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, see page 13 of the Response, with respect to the provisional double patenting rejection over claims 1 – 8, 12 – 15, 19, 20, 38 – 42, 44, 47 – 49 and 52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 11/187,757, have been fully considered but they are not persuasive. The rejection has been MAINTAINED for reasons set forth in the Office Action mailed 5/11/07.

Applicant's arguments, see page 14 of the Response, with respect to the rejection(s) of claim(s) 1 – 22 under 35 USC 102(b) as being anticipated by Weers (WO

99/16422), as evidenced by Block, have been fully considered. Therefore, the rejection has been WITHDRAWN as being overcome by amendment.

Applicant's arguments, see page 15 of the Response, with respect to the rejection(s) of claim(s) 1 – 5, 7, 8, 12 – 15, 17, 18, 20 – 22, 38 – 44, 46 – 49, 51, 53, 69 – 75, 77 – 79, 81 and 83 under 35 USC 102(b) over Kim have been fully considered and are persuasive. Therefore, the rejection has been WITHDRAWN.

Applicant's arguments, see page 16 of the Response, with respect to the rejection(s) of claim(s) 1 – 8, 12 – 18, 38 – 44, 46 – 51, 53, 69 – 75 and 77 – 81 under 35 USC 102(b) as being anticipated by Knight have been fully considered and are persuasive. Therefore, the rejection has been WITHDRAWN.

Applicant's arguments, see page 17 of the Response, with respect to the rejection(s) of claim(s) 1 – 22 and 38 – 83 under 35 USC 102(e) as being anticipated by Weers (US 2002/00179295) have been fully considered and are persuasive. Therefore, the rejection has been WITHDRAWN. However, upon further consideration, a new ground(s) of rejection is made in view of further consideration of the prior art, as set forth hereinbelow.

Applicant's arguments, see page 17 – 18 of the Response, with respect to the rejection(s) of claim(s) 1 – 22 and 38 – 83 under 35 USC 103(a) as being unpatentable

over Weers (US 2002/00179295) in view of Cicogna have been fully considered and are persuasive. Therefore, the rejection has been WITHDRAWN.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to formulations according to claims 1 and 38, respectively, and the particulates are suspended in a propellant for aerosolization in a metered dose inhaler. However, independent claims 1 and 50 are drawn to particulates "consisting essentially of" an active agent in a phospholipid matrix. The components of the composition are unclear because the independent claims appear to preclude the presence of additional agents, such as a propellant.

Claims 17 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to formulations according to claims 1 and 38, respectively, and the particulates are suspended in a liquid for aerosolization in a nebulizer. However, independent claims 1 and 50 are drawn to a

pharmaceutical formulation for pulmonary administration as a powder. The components of the composition are unclear because the independent claims appear to indicate that the formulation is in a dry form, while the dependent claims require a liquid, which is contradictory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 22, 38 – 42, 44, 47 – 56, 58, 60, 62 - 68 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent).

Weers discloses dry powder compositions of phospholipids which are efficiently delivered to the deep lung. The phospholipids may be administered alone or in combination with an active agent. The composition may be administered via a simple

passive DPI device (paragraph 0011). The active agent may be ciprofloxacin, amphotericin (i.e. which inherently has the claimed solubility), tobramycin (paragraph 0022). The medicament possess special physicochemical properties, such as high crystallinity (paragraph 0060), and include hollow porous aerodynamically light microparticles with particle diameters appropriate for aerosol deposition into the lung (paragraph 0065 and 0048).

The medicament is formulated in a way such that it readily disperses into discrete particles with an **MMD** which is preferably from **0.5 – 5 μm** (i.e. less than 10 μm , as claimed); a **MMAD** preferably from **1 – 4 μm** (i.e. including less than about 2.6 μm , as claimed) (paragraph 0043). The powders typically have a **bulk density** less than 0.1 g/cm^3 , or preferably less than **0.05 g/cm^3** , as claimed (paragraph 0049). The **geometric particle size** is preferably less than **2.5 μm** (i.e. which is less than 3 μm , as claimed) (paragraph 0070).

Phospholipids from both natural and synthetic sources are compatible with the present invention and may be used in varying concentrations to form the structural matrix. Exemplary phospholipids useful in the disclosed stabilized preparations include dipalmitoylphosphatidylcholine, distearylphosphatidylcholine, etc. (paragraph 0032). Regarding claim 19, the powders can include a polyvalent cation (abstract). Regarding claim 3, the emitted dose is 94% (paragraph 0098). Regarding claim 6, the dosage may be 5 mg (paragraph 0023). Regarding claims 15 – 17, the particulate compositions may be used in conjunction with metered dose inhalers, dry powder inhalers or

nebulizers for liquid dose instillation techniques (paragraph 0042). Regarding claim 21, the particles are made by spray-drying with a blowing agent (paragraph 0058).

Regarding claims 4 and 5, it is noted that Weers does not specifically recite a fine particle fraction of his formulation, and does not specifically depict a figure regarding Ostwald ripening. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. It is interpreted, absent evidence to the contrary, that since Weers discloses particles of the same active agents (i.e. thus having the same solubility), and teaches that the particles are the same sizes (i.e. MMD, MMAD and geometric diameters) less than those is claimed, same bulk density, etc., and are made by the same methods as those claimed, the particles would inherently be capable of having the claimed inherent features such as fine particle fraction or Ostwald ripening.

Weers does not specifically teach that at least 90% of the active agent particles have the claimed diameter and bulk density properties.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to maximize the number of particles meeting the preferred particle size and density parameters taught by Weers. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because one skill in the art would desire that the vast majority, if not all, of the particles used in the formulation would be homogenous so as to maximize desirable characteristics because

Weers specifically teaches that narrow particle size distributions are preferred and are believed to be an indication of the powder's ability to deaggregate (paragraph 0087).

Conclusion


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER